

IN THE CLAIMS:

1. (Currently amended) A method for detecting, inferring, or monitoring a neoplastic disease in a human ~~or animal~~, wherein said neoplastic disease is associated with the expression or overexpression of one or more RNA species, the method comprising the steps of:
  - a) extracting total extracellular RNA from plasma or serum of a human ~~or animal~~;
  - b) amplifying or signal amplifying quantitatively or qualitatively a portion of the extracted RNA or cDNA therefrom to produce an amplified product or signal, using primers or probes specific for RNA or cDNA therefrom, wherein said RNA is expressed or overexpressed in a neoplastic disease;
  - c) detecting quantitatively or qualitatively the amplified product or signal and comparing the amplified product or signal to a reference determined from a human group or population,wherein a neoplastic disease is detected, inferred or monitored in a human when the amplified product or signal of one or more RNA or cDNA therefrom is detected in an amount or concentration greater than the reference amount or concentration for said RNA or cDNA therefrom determined from a human group or population without said neoplastic disease, and/or when the amplified product or signal of one or more RNA or cDNA therefrom is detected in an amount or concentration not less than the reference amount or concentration for said RNA or cDNA therefrom determined from a human group or population with said neoplastic disease.
2. (Currently amended) The method of claim 1, wherein the neoplastic disease is cancer or premalignancy.

3. (Withdrawn) The method of claim 1, wherein the amplified product is produced from a non-tumor related RNA or cDNA produced therefrom.
4. (Original) The method of claim 1, wherein the amplified product is produced from a tumor related RNA or cDNA produced therefrom.
5. (Currently amended) A method for detecting, inferring, or monitoring a neoplastic disease in a human ~~or animal~~, wherein said neoplastic disease is associated with the expression or overexpression of one or more RNA species, the method comprising the steps of:
  - a) extracting total RNA from a non-cellular fraction of a ~~body fluid~~ blood from a human ~~or animal~~;
  - b) amplifying or signal amplifying quantitatively or qualitatively a portion of the extracted RNA or cDNA therefrom to produce an amplified product or signal, using primers or probes specific for RNA or cDNA therefrom, wherein said RNA is expressed or overexpressed in a neoplastic disease;
  - c) detecting quantitatively or qualitatively the amplified product or signal and comparing the amplified product or signal to a reference determined from a human group or population,

wherein a neoplastic disease is detected, inferred or monitored in a human when the amplified product or signal of one or more RNA or cDNA therefrom is detected in an amount or concentration greater than the reference amount or concentration determined from a human

group or population without said neoplastic disease, and/or when the amplified product or signal of one or more RNA or cDNA therefrom is detected in an amount or concentration not less than the reference amount or concentration determined from a human group or population with said neoplastic disease.

6. (Currently amended) The method of claim 5, wherein the neoplastic disease is cancer or premalignancy.
7. (Withdrawn) The method of claim 5, wherein the amplified product is produced from a non-tumor related RNA or cDNA produced therefrom.
8. (Original) The method of claim 5, wherein the amplified product is produced from a tumor related RNA or cDNA produced therefrom.
9. (Currently amended) A method to detect, infer, or monitor a disease in a human ~~or~~ animal, the method comprising the steps of determining an amount or concentration or comparative value of total extracellular RNA or one or a plurality of an RNA species in a portion of plasma or serum from the human or animal, and comparing the amount or concentration or comparative value of total extracellular RNA or one or a plurality of an RNA species to a reference range RNA amount, concentration, or value determined from a defined group or population.

10. (Withdrawn) The method of claim 9, wherein the defined group or population comprises healthy humans.
11. (Withdrawn) The method of claim 9, wherein the defined group or population comprises healthy animals.
12. (Currently amended) The method of claim 9, wherein the ~~defined~~ group or population with a neoplastic disease comprises humans with cancer.
13. (Cancelled)
14. (Currently amended) The method of claim 9, wherein the ~~defined~~ group or population with a neoplastic disease comprises humans with ~~neoplasia~~ pre malignancy.
15. (Cancelled)
16. (Currently amended) The method of claim [9] 12, wherein the ~~defined group~~ group or population comprises humans of a specific cancer type or stage.
17. (Original) The method of claim 9, wherein the defined group or population comprises humans of a specific gender or age group.

18. (Original) The method of claim 9, wherein the defined group or population comprises humans who smoke.
19. (Withdrawn) The method of claim 9, wherein the defined group or population comprises humans with a family or genetic history of cancer or cancer risk.
20. (Currently amended) A method to detect, infer, or monitor neoplastic disease in a human ~~or animal~~, the method comprising the steps of determining an amount or concentration or comparative value of total extracellular RNA or one or a plurality of tumor-associated RNA species in a portion of a non-cellular fraction of ~~a bodily fluid~~ blood from the human ~~or animal~~, and comparing to a reference range RNA amount, concentration, or value determined from a defined human group or population, wherein a neoplastic disease is detected, inferred, or monitored in a human when the amount or concentration or comparative value of total extracellular RNA or one or a plurality of tumor-associated RNA in said human is greater than a defined reference range RNA amount, concentration, or value determined from a human group or population without neoplastic disease, and/or when the amount or concentration or comparative value of total extracellular RNA or one or a plurality of tumor-associated RNA in said human is greater than a reference range RNA amount, concentration, or value determined from a human group or population with a neoplastic disease.
21. (Withdrawn) The method of claim 20, wherein the defined group or population comprises healthy humans.

22. (Withdrawn) The method of claim 20, wherein the defined group or population comprises healthy animals.
23. (Currently amended) The method of claim 20, wherein the ~~defined~~ group or population with a neoplastic disease comprises humans with cancer.
24. (Cancelled)
25. (Currently amended) The method of claim 20, wherein the ~~defined~~ group or population with a neoplastic disease comprises humans with ~~neoplasia~~pre-malignancy.
26. (Cancelled)
27. (Currently amended) The method of claim [20] 23, wherein the ~~defined~~ group or population comprises humans of a specific cancer type or stage.
28. (Original) The method of claim 20, wherein the defined group or population comprises humans of a specific sex or age group.
29. (Original) The method of claim 20, wherein the defined group or population comprises humans who smoke.

30. (Withdrawn) The method of claim 20, wherein the defined group or population comprises humans with a family or genetic history of cancer or cancer risk.
31. (Currently amended) A method of evaluating a human ~~or animal~~ for a neoplastic disease, the method comprising the step of assaying quantitatively blood plasma or serum from the human ~~or animal~~ to determine an amount or concentration of a housekeeping gene RNA, whereby determination of the amount or concentration of a housekeeping gene RNA in the presence or absence of tumor-associated RNA in blood plasma or serum from said human thereby evaluates a human for a neoplastic disease.
32. (Currently amended) A method of evaluating a human ~~or animal~~ for a neoplastic disease, comprising the step of assaying quantitatively non-cellular fraction of a ~~body fluid~~ blood from the human ~~or animal~~ to determine an amount or concentration of a housekeeping gene RNA, whereby determination of the amount or concentration of a housekeeping gene RNA in the presence or absence of tumor-associated RNA in blood plasma or serum from said human thereby evaluates a human for a neoplastic disease.
33. (Withdrawn) A method of evaluating a human or animal for a disease comprising the step of assaying quantitatively blood plasma or serum from the human or animal to determine an amount or concentration of a non-tumor related RNA.

34. (Withdrawn) A method of evaluating a human or animal for a disease comprising the step of assaying quantitatively non-cellular fraction of a bodily fluid from the human or animal to determine an amount or concentration of a non-tumor related RNA.
35. (Withdrawn) A kit for identifying or selecting a human or animal with a disease, wherein the kit provides reagents for detecting an amount or concentration of total extracellular RNA or one or a plurality of an RNA species thereof in plasma or serum in blood plasma or serum and a reference range of normal values of total extracellular RNA or one or a plurality of an RNA species thereof.
36. (Withdrawn) A kit for identifying or selecting a human or animal with a disease, wherein the kit provides reagents for detecting an amount or concentration of total extracellular RNA or one or a plurality of an RNA species thereof in plasma or serum in blood plasma or serum and a reference range of values from an individual, group or population with the disease of total extracellular RNA or one or a plurality of an RNA species thereof.
37. (Withdrawn) A kit according to claim 35 wherein the disease is cancer or premalignancy.
38. (Withdrawn) A kit according to claim 36 wherein the disease is cancer or premalignancy.
39. (Cancelled)



- 40. (Cancelled)
- 41. (Cancelled)
- 42. (Cancelled)
- 43. (Cancelled)
- 44. (Cancelled)
- 45. (Currently amended) The method of claim 9, wherein the neoplastic disease is cancer or premalignancy.
- 46. (Currently amended) The method of claim 20, wherein the neoplastic disease is cancer or premalignancy.
- 47. (Currently amended) The method of claim 31, wherein the neoplastic disease is cancer or premalignancy.
- 48. (Currently amended) The method of claim 32, wherein the neoplastic disease is cancer or premalignancy.
- 49. (Withdrawn) The method of claim 33, wherein the disease is cancer or premalignancy.
- 50. (Withdrawn) The method of claim 34, wherein the disease is cancer or premalignancy.